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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,522	03/09/2004	Joseph F. Poduslo	01017/30016A	2632

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EXAMINER	
CHERNYSHEV, OLGA N	
ART UNIT	**PAPER NUMBER**
1649	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,522	PODUSLO ET AL.	
	Examiner	Art Unit	
	Olga N. Chernyshev	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31,33-48 and 51-73* is/are pending in the application.

4a) Of the above claim(s) *47 and 51-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31, 33-46, 48 and 67-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 04/22/08
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 30, 2007 has been entered.

Response to Amendment

2. Claim 31 has been amended and claim 73 has been added as requested in the amendment filed on October 30, 2007. Following the amendment, claims 31, 33-48 and 51-73 are pending in the instant application.

Claims 47 and 51-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

Claims 31, 33-46, 48 and 67-73 are under examination in the instant office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on June 13, 2007 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 31, 33-46, 48 and 72-73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 31, as currently presented, and new claim 73 are vague and indefinite for recitation "a clinically recognized improvement or stabilization of one or more clinical features of a CNS disorder in a statistically significant number of patients". The metes and bounds of the recitation cannot be determined from the claims or the instant specification, as filed. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "therapeutic non-Aβ polypeptides [which] provide[s] a clinically recognized improvement or stabilization of one or more clinical features of a CNS disorder in a statistically significant number of patients", an artisan cannot determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. Clarification is required.

8. Claim 43 is indefinite for reciting Aβ polypeptide 1-39 of SEQ ID NO: 1 while being dependent from claims 70 and 72, which specifically require substitutions within Aβ of SEQ ID NO: 1, which makes the subject matter of claim 43 mutually exclusive.

9. Similarly, claims 45 and 46 recite Aβ polypeptide with substitutions wherein the base claim 31 is limited to Aβ polypeptide, which is known in the art to be defined by SEQ ID

NO: 1. Thus, the claims lack antecedent basis for reciting different structure not present in the claim from which they depend.

10. Claims 48 and 72 are vague and ambiguous for reciting specific characteristics of the claimed composition in terms related to "permeability", PS product, "the protein", "different brain regions" and adjustment of the reading after correction. The presence of the limitation appears to have no effect on the limiting structural characteristics of the claimed product. Applicant is advised that the recitation of characteristics of the composition of claims 48 and 78 is either inherent to the composition, or that the instant specification fails to provide enablement as how to produce that specific compositions that meet the limitations of the claims.

11. Claims 33-44 are indefinite for being dependent from indefinite claim.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 31, 33-35, 43, 48, 69 and 72-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Solomon et al., 1997, PNAS USA, Vol. 94, pp.4109-12.

Claims 31, 33-35, 43, 48, 69 and 72-73 are directed to a composition comprising an amyloid beta (Aβ) polypeptide linked to a therapeutic non-Aβ polypeptide. At p. 6, second paragraph, the instant specification discloses the following.

"Alternatively, an Aβ polypeptide can be linked to a non- Aβ polypeptide such as an antibody via the specific binding affinity of the antibody for the Aβ polypeptide. Purified Aβ polypeptide and antibody can be incubated together at 37°C in an appropriate buffer (e.g., phosphate buffered saline) to form an immune complex. Such an immune complex constitutes a composition of the invention". (Emphasis added by the Examiner).

Thus, by broadest reasonable interpretation and in agreement with the specification, the instant claimed composition of claims 31, 33-40, 43-46, 48 and 69-73 encompasses immune complex formed between different Aβ polypeptides and antibodies specific for Aβ polypeptide.

Publication of Solomon et al. teaches immune complexes between Aβ and monoclonal antibody 6C6, which were used to treat the cells in culture ("sterile and pharmaceutically acceptable carrier", see limitation of claim 31), see pp. 4109-10, Materials and methods, pp. 4111 and Figure 5. Thus, Solomon et al. fully meet the limitations of the instant claimed subject matter.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. Claims 36-40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon et al., 1997.

17. Claims 36-40 are directed to Aβ polypeptides linked to antibodies, which are chimeric, humanized and fragments. Document of Solomon et al. teaches immune complexes of Aβ polypeptides and antibodies to Aβ, see reasons of record in section 13 of the instant office action. Solomon et al. do not expressly teach Aβ polypeptides linked to antibodies, which are chimeric, humanized and fragments. At the time of invention, the art of production of antibodies, such as monoclonal, polyclonal, chimeric, including humanized as well as producing fragments of antibodies, is considered to be well-described and widely used. It would have been obvious for one of ordinary skill in the art to substitute an antibody to Aβ polypeptide for any of the chimeric, humanized or antibody fragments to produce an immune complex of Solomon et al. One skilled in the art would have been motivated to do so because it was well within the technical grasp of one of ordinary skill in the art to substitute one form of antibody for another to obtain the same and predictable result of producing an immune complex of Aβ and an antibody to Aβ.

18. Claim 44 is directed to Aβ 1-42 polypeptides linked to an antibody to Aβ polypeptide. The article of Solomon et al. teaches only one example of Aβ polypeptide, 1-40, and not specifically 1-42. However, at the time of invention, the art clearly recognized fragments of Aβ polypeptides, 1-39, 1-40 and 1-42, as virtually obvious variants of each other. Therefore, at the time of invention, it would have been obvious for one of ordinary skill in the art to use Aβ polypeptide 1-42 instead of 1-40, as recited by Solomon et al. to create immune complexes between Aβ polypeptide and anti-Aβ antibodies. One of ordinary skill in the art would have been motivated to do this because of the recognition that the results of such substitution would lead to the same and predictable results.

Claim Rejections - 35 USC § 102

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. Claims 31, 33 and 42-43, 45-46, 48, 67-68 and 70-73 are rejected under 35 U.S.C. 102(b) as being anticipated by Schenk, 1999, WO99/27944 for reasons of record as applied to claims 31 and 42-45 in section 5 of Paper mailed on August 28, 2007.

Applicant traverses the rejection on premises that "[t]he Examiner has not pointed out to any teaching in Schenk that the polypeptide fused or conjugated to Aβ (i.e., the non-Aβ polypeptide) provides a clinically recognized improvement or stabilization of one or more clinical features of a CNS disorder in a statistically significant number of patients, as recited in claim 31" (p. 8 of the Response). Applicant's argument has been fully considered but is not persuasive because the limitation cited by Applicant as distinguishing feature appeared only in the instant amended claim 31; this limitation is addressed by the Examiner in section 7 of the instant office action: Because the instant specification teaches non-Aβ polypeptides as any polypeptide (see p. 6), the claims are interpreted as broadly directed to fusion proteins of Aβ and "non-Aβ polypeptide". Schenk document fully discloses different length and substituted varieties of Aβ polypeptides linked/fused with other polypeptides ("compositions comprising Aβ or an active fragment linked to a conjugate molecule that promotes delivery of Aβ to the bloodstream of a patient and/or promotes an immune response against Aβ", see pp. 4-5 of Schenk document; see also pp. 19-20), thus fully anticipating the instant invention.

Conclusion

21. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

January 22, 2008